

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
7 June 2001 (07.06.2001)

PCT

(10) International Publication Number
WO 01/40269 A3

(51) International Patent Classification⁷: **C07K 14/47**,
16/30, A61K 38/00, 39/39, 45/00, G01N 33/53, 33/531,
33/574

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(21) International Application Number: PCT/US00/32520

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(22) International Filing Date:

29 November 2000 (29.11.2000)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

09/451,651	30 November 1999 (30.11.1999)	US
09/510,662	22 February 2000 (22.02.2000)	US
09/523,586	10 March 2000 (10.03.2000)	US
09/545,068	7 April 2000 (07.04.2000)	US
09/571,025	15 May 2000 (15.05.2000)	US

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU,
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ,
DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR,
HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR,
LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ,
NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM,
TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM,
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian
patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European
patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE,
IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF,
CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

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Published:

— with international search report

(88) Date of publication of the international search report:
13 December 2001

*For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.*



WO 01/40269 A3

(54) Title: COMPOSITIONS AND METHODS FOR THERAPY AND DIAGNOSIS OF BREAST CANCER

(57) Abstract: Compositions and methods for the therapy and diagnosis of cancer, such as breast cancer, are disclosed. Compositions may comprise one or more breast tumor proteins, immunogenic portions thereof, or polynucleotides that encode such portions. Alternatively, a therapeutic composition may comprise an antigen presenting cell that expresses a breast tumor protein, or a T cell that is specific for cells expressing such a protein. Such compositions may be used, for example, for the prevention and treatment of diseases such as breast cancer. Diagnostic methods based on detecting a breast tumor protein, or mRNA encoding such a protein, in a sample are also provided.

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INTERNATIONAL SEARCH REPORT

International Application No

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A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 C07K14/47 C07K16/30 A61K38/00 A61K39/39 A61K45/00
 G01N33/53 G01N33/531 G01N33/574

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 C07K A61K G01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, BIOSIS, EMBASE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99 33869 A (CORIXA CORP) 8 July 1999 (1999-07-08) Example 2 in connection with pages 15 to 17	35,36
Y	Example 1	1-34, 37-59
X	WO 99 37775 A (GENQUEST INC) 29 July 1999 (1999-07-29) See the whole document, in connection with page 21 -page 28	35,36
Y	Page 5 et sequentia	1-34, 37-59
Y	WO 97 25431 A (CORIXA CORP) 17 July 1997 (1997-07-17) the whole document	1-59
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☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

& document member of the same patent family

Date of the actual completion of the international search

20 April 2001

Date of mailing of the international search report

09.07.01

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 00/32520

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	DIATCHENKO L ET AL: "SUPPRESSION SUBSTRUCTIVE HYBRIDIZATION: A METHOD FOR GENERATING DIFFERENTIALLY REGULATED OR TISSUE-SPECIFIC CDNA PROBES AND LIBRARIES" PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF USA,US,NATIONAL ACADEMY OF SCIENCE. WASHINGTON, vol. 93, 1 June 1996 (1996-06-01), pages 6025-6030, XP002911922 ISSN: 0027-8424 Abstract, discussion, page 1520 et sequentia ---	1-12, 57-59
Y	LEE S W ET AL: "POSITIVE SELECTION OF CANDIDATE TUMOR-SUPPRESSOR GENES BY SUBSTRUCTIVE HYBRIDIZATION" PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF USA,US,NATIONAL ACADEMY OF SCIENCE. WASHINGTON, vol. 88, 1 April 1991 (1991-04-01), pages 2825-2829, XP002048608 ISSN: 0027-8424 Abstract page 2826, column 2, paragraph 6 -page 2828, column 1, paragraph 1 ---	1-59
Y	BURGER A ET AL: "BREAST CANCER GENOME ANATOMY: CORRELATION OF MORPHOLOGICAL CHANGES IN BREAST CARCINOMAS WITH EXPRESSION OF THE NOVEL GENE PRODUCT D112" ONCOGENE,GB,BASINGSTOKE, HANTS, vol. 16, 22 January 1998 (1998-01-22), pages 327-333, XP002914258 ISSN: 0950-9232 the whole document ---	1-59
Y	SCHLOM J ET AL: "STRATEGIES FOR THE DEVELOPMENT OF RECOMBINANT VACCINES FOR THE IMMUNOTHERAPY OF BREAST CANCER" BREAST CANCER RESEARCH AND TREATMENT,US,NIJHOFF, BOSTON, vol. 38, no. 1, 1996, pages 27-39, XP000578043 ISSN: 0167-6806 the whole document ---	1-59
Y	WO 99 14230 A (FLEMING TIMOTHY P ;WATSON MARK A (US); UNIV WASHINGTON (US)) 25 March 1999 (1999-03-25) the whole document -----	1-59

INTERNATIONAL SEARCH REPORT

national application No.
PCT/US 00/32520

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
Although claims 20, 21, 28-30, 33, 34, 36-38 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☒ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-59 (party)

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-59 (partly)

Invention 1.

Isolated polypeptide comprising at least an immunogenic portion of a breast tumour protein, variants thereof such that the ability of variant to react with antigen-specific antisera is not substantially diminished, wherein the tumour protein comprises an amino acid sequence that is encoded by polynucleotide sequence SEQ. ID. NO: 2. or its complement; isolated encoding polynucleotide, expression vector, host cell transformed therewith; antibody specifically binding thereto; fusion proteins; pharmaceutical compositions and vaccines; therapeutic methods and methods of inhibiting growth/development of and removing tumour cells from a biological sample; methods of stimulating and/or expanding T cells specific; T cell populations prepared according to method; use thereof in therapy; diagnostic methods, Kits; oligonucleotides comprising 10-40 contiguous nucleotides that hybridise to SEQ ID NO: 2, kits containing same.

2. Claims: 1-59 (partly)

Inventions 2-284

As above, but respectfully referring to sequences 1,3-38, 42-204,205,207,210-290.

Note that sequences

1,6,8,9,11,12,14,17-20,22-24,26,27,29,31,32,34,36,37,38,42-62,64-71,74-80,82-102,105,106,110-117,119-127,130-133,135,137-158,162,163,165-180,182,205-207 are only mentioned in claims 24-52 per se.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box 1.2

Present claims 1(b),57..... relate to an oligonucleotide comprising 10 to 40 contiguous nucleotides that hybridise under moderately stringent conditions to a polynucleotide (SEQ ID NO:2)

The claims cover all oligonucleotides having this property, whereas the application provides support within the meaning of Article 6 PCT and/or disclosure within the meaning of Article 5 PCT for only a very limited number of same. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. Independent of the above reasoning, the claims also lack clarity (Article 6 PCT). An attempt is made to define the oligonucleotide by reference to a result to be achieved. Again, this lack of clarity in the present case is such as to render a meaningful search over the whole of the claimed scope impossible. Consequently, the search has been carried out for those parts of the claims which appear to be clear, supported and disclosed, namely those parts relating to the SEQ ID NO:2 per se.

Present claims 1,3..... relate to a variant encoded by SEQ ID NO 2 defined by reference to a desirable characteristic or property, namely "variants of said isolated polypeptide, the ability of the variant to react with antigen-specific antisera not being substantially diminished"

The claims cover all variants having this characteristic or property, whereas the application provides support within the meaning of Article 6 PCT and/or disclosure within the meaning of Article 5 PCT for only a very limited number of such products. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. Independent of the above reasoning, the claims also lack clarity (Article 6 PCT). An attempt is made to define the variants by reference to a result to be achieved. Again, this lack of clarity in the present case is such as to render a meaningful search over the whole of the claimed scope impossible. Consequently, the search has been carried out for those parts of the claims which appear to be clear, supported and disclosed, namely those parts relating to the SEQ ID NO: 2 per se, mentioned in the exemplification, sequence listing and claims. The claim set has been searched with this in mind.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter national Application No

PCT/US 00/32520

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9933869 A	08-07-1999	AU 2010699 A EP 1042360 A ZA 9811800 A	19-07-1999 11-10-2000 23-06-1999
WO 9937775 A	29-07-1999	AU 2342299 A	09-08-1999
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WO 9914230 A	25-03-1999	US 5922836 A AU 9373798 A BR 9812472 A CN 1277614 T EP 1037901 A HU 0004022 A NO 20001358 A PL 340689 A TR 200001646 T	13-07-1999 05-04-1999 19-09-2000 20-12-2000 27-09-2000 28-03-2001 12-05-2000 26-02-2001 23-10-2000